

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison stage of vaginal delivery in painless labor with epidural & spinal analgesia

Protocol summary

Summary

The aim of this study was to compare two methods of labor with epidural and spinal analgesia in pregnant women in Taleghani Hospital in Arak. In this study, 90 patients were randomly divided into three groups: epidural analgesia in labor, spinal analgesia in labor and control group. Inclusion criteria: All pregnant women between 37-42 weeks; ASA class I and II; prim gravida; cervical dilation 3-4 cm; absence of fever and systemic infection or other disease; lack of coagulopathy; age 18-40. Exclusion criteria: failure epidural and spinal analgesia; sensitivity to opioids; mothers with gestational age below 37 weeks; mothers with multiple fetus. Cervix dilation record in delivery. Vital signs, oxygen saturation, blood pressure and breathing rate maternal and fetal heart rate record every 15 minutes. After delivery, researcher records Apgar score, fetal heart rate and vital signs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050420258N8**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Science

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison stage of vaginal delivery in painless labor with epidural & spinal analgesia

Public title

Comparison stage of vaginal delivery in painless labor with epidural & spinal analgesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All pregnant women gestational age between 37-42 weeks; ASA class I and II; primigravida; dilatation of cervix 3-4 cm; lack of systemic infection or fever and other diseases; lack of sensitivity opioid; absence of coagulopathy; age 18-40. Exclusion criteria: ASA class two and three; failure epidural and spinal anesthesia; sensitivity to opioid; mothers with gestational age below 37 weeks; mothers with more than one fetus

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Postal code

Approval date

2016-02-22, 1394/12/03

Ethics committee reference number

IR.ARAKMU.REC.1394.297

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80.8

ICD-10 code description

Other single spontaneous delivery

Primary outcomes

1

Description

oxygen saturation

Timepoint

every 15 minute

Method of measurement

oxymeter

2

Description

heart rate

Timepoint

every 15 minute

Method of measurement

count

3

Description

respiratory rate

Timepoint

every 15 minute

Method of measurement

count

4

Description

Fetal heart rate

Timepoint

every 15 minute

Method of measurement

sony cate

5

Description

Labor progress

Timepoint

every 15 minute

Method of measurement

centimeter

6

Description

Apgar

Timepoint

After delivery

Method of measurement

Apgar scale

Secondary outcomes

empty

Intervention groups

1

Description

The first group of 30 pregnant women have an epidural.

Category

Diagnosis

2

Description

In the control group of 30 pregnant women delivery without anything.

Category

Diagnosis

3

Description

In the second group involved 30 pregnant women receiving spinal anesthesia.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Maryam Shokrpour

Street address

Taleghani hospital, Emam Khomeini street

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University Of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Arak University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Anesthesiologist

Other areas of specialty/work

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

Email

alikalami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Anesthesiologist

Other areas of specialty/work

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

Email

alikalami@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Yazdan Ghandi

Position

student of medicine

Other areas of specialty/work

Street address

Arak medical science university

City

Arak

Postal code

848176941

Phone

+98 912 383 3712

Fax**Email**

fa.farokhi@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*